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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,346	09/23/2005	Fabrice Le Gall	03528.0146.PCUS00	7228

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EXAMINER	
SKELDING, ZACHARY S	
ART UNIT	**PAPER NUMBER**
1644	

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05/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,346	LE GALL ET AL.	
	Examiner	Art Unit	
	ZACHARY SKELDING	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and election filed February 11, 2008 is acknowledged.

   Claims 5 and 13 have been amended.

   Claims 18 and 19 have been added.

   Claims 1-19 are pending.

   Applicant's election of Group I drawn to a bivalent or multivalent antibody that binds an epitope on CD3 and the species of bivalent or multivalent antibody that is a "diabody" in the reply filed on February 11, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

   Thus, claims 1-3 and 5-8 are under examination as they read on a bivalent or multivalent antibody that binds an epitope on CD3 and the species of bivalent or multivalent antibody that is a "diabody".

   Accordingly, claims 4 and 9-19 are withdrawn further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group or species of invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 11, 2008.

   Nevertheless, upon further consideration it has been determined that the invention as claimed is directed to more than one species of the generic invention. Furthermore, applicant's amendment of claim 13 (and new claims 18 and 19) has changed the Grouping of inventions.

   Therefore the previous Restriction Requirement is hereby VACATED.

   A New Restriction and Election of Species Requirement is put forth below.

   The Examiner apologizes to Applicant for any inconvenience in this matter.

Restriction Requirement

2. Restriction is required under 35 U.S.C. 121 and 372.

3. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

   Group I, claim(s) 1-8, 13, 18 and 19 drawn to a bivalent or multivalent antibody that binds an epitope on CD3 and pharmaceutical compositions thereof.

Group II, claim(s) 9-12, drawn to a polynucleotide which encodes a bivalent or multivalent antibody that binds an epitope on CD3, expression vectors comprising said polynucleotide and host cells thereof.

Group III, claims 14-16, drawn to a method for immunotherapy comprising the step of administering the antibody of claim 1 or a pharmaceutical composition thereof.

Group IV, claims 17, drawn to a method for gene therapy comprising the step of administering the polynucleotide or expression vector of claims 9-10.

4. The inventions listed as Groups I-IV above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the invention of Group I, for example, was found to have no special technical feature that defined the contribution over the prior art of Holliger et al. (U.S. Patent No. 7,122,646, of record) which teaches a bivalent anti-CD3 diabody which is capable of suppressing an immune reaction and is devoid of constant antibody regions (see, in particular Example 17, columns 55-57).

   Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

5. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Species Election

6. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

7. If applicant elects Group I, applicant is required to elect a particular species of bivalent or multivalent antibody from among the species recited in claims 2-4 and in the instant specification at pages 3 and 9, 1st paragraph from among the following A-D:

   A. The antibody is the product of non-covalent dimerization or multimerization of single chain Fv antibodies and the antibody comprises two or more scFv antibodies wherein the Vh and Vl domains of each scFv are separated by peptide linkers that enable intramolecular pairing between the Vh and Vl domains of a given scFv antibody, i.e., conventional antibody Vh/Vl pairing.

   B. The antibody is the product of covalent dimerization or multimerization of single chain Fv antibodies and the antibody comprises two or more scFv antibodies wherein the Vh and

Vl domains of each scFv are separated by peptide linkers that enable intramolecular pairing between the Vh and Vl domains of a given scFv antibody, i.e., conventional antibody Vh/Vl pairing.

C. The antibody is the product of non-covalent dimerization or multimerization of single chain Fv antibodies and the antibody comprises two or more scFv antibodies wherein the Vh and Vl domains of each scFv are separated by peptide linkers or by no linkers in an orientation preventing their intramolecular pairing, i.e., the diabody format.

D. The antibody is the product of covalent dimerization or multimerization of single chain Fv antibodies and the antibody comprises two or more scFv antibodies wherein the Vh and Vl domains of each scFv are separated by peptide linkers or by no linkers in an orientation preventing their intramolecular pairing, i.e., the diabody format.

These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

8. If applicant elects either Group III or IV, applicant is required to elect a particular species of target subject to receive the therapy selected from among the target subject species recited, for example, in claim 16 wherein the target subject species is has or is at risk of having "acute transplant rejection," or for example, in the instant specification at page 16, 3rd paragraph such as "type I diabetes" or "rheumatoid arthritis".

   These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

   Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

9. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

   The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall

be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
April 28, 2008

/Michail A Belyavskyi/
Primary Examiner, Art Unit 1644